IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBVIE INC. and ABBVIE DEUTSCHLAND GMBH & CO. KG,	)	
Plaintiffs,	)	
	)	C.A. No. _____
v.	)	
HETERO USA INC. and HETERO LABS LIMITED,	)	
Defendants.	)	

COMPLAINT

Plaintiff AbbVie Inc. and AbbVie Deutschland GmbH & Co. KG (collectively "AbbVie"), by way of Complaint against Hetero USA Inc. and Hetero Labs Limited, state as follows:

THE PARTIES

1. Plaintiff AbbVie Inc. ("AbbVie") is a corporation organized and existing under the laws of Delaware with its corporate headquarters at 1 North Waukegan Road, North Chicago, Illinois 60064. AbbVie is a global biopharmaceutical company engaged in the business of research, development, manufacture, and sale of pharmaceutical products throughout the world.

2. Plaintiff AbbVie Deutschland GmbH & Co. KG is a partnership organized and existing under the laws of Germany with its registered seat at Mainzer Straße 81, 65189 Wiesbaden, Germany. AbbVie Deutschland GmbH & Co. KG is governed by its General Partner, AbbVie Komplementaer GmbH, Wiesbaden, Germany, and is a wholly-owned subsidiary of AbbVie Inc.

3. On information and belief, Defendant Hetero USA Inc. ("Hetero USA") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1035 Centennial Avenue, Piscataway, New Jersey 08854, and is registered to do business in Delaware, including its appointment of a registered agent in Delaware (located at W/K Incorporating Services, Inc., 3500 South Dupont Highway, Dover, DE 19901) for the receipt of service of process.

4. On information and belief, Defendant Hetero Labs Limited ("Hetero Labs") is an Indian corporation having a principal place of business at 22-110, IDA, Jeedimetla, Hyderabad-500055.

5. On information and belief, Hetero Labs is a parent corporation of Hetero USA.

6. On information and belief, Hetero USA acts as the agent of Hetero Labs.

7. On information and belief, Hetero Labs and Hetero USA manufacture and sell various generic drug products and regularly conduct business throughout the United States, including in the State of Delaware.

NATURE OF THE ACTION

8. This is a civil action for patent infringement of United States Patent Number 8,470,347 B2 ("the '347 patent") and United States Patent Number 8,399,015 B2 ("the '015 patent"), arising under the United States Patent Laws, Title 35, United States Code, §100, *et seq.*, and in particular under 35 U.S.C. § 271. This action relates to Abbreviated New Drug Application ("ANDA") No. 204587, which Hetero USA and Hetero Labs filed or caused to be filed under 21 U.S.C. § 355(j) with the United States Food and Drug Administration ("FDA"), for approval to market a generic copy of AbbVie's successful Norvir® tablets that are sold in the United States, and which Hetero USA and Hetero Labs subsequently amended.

JURISDICTION AND VENUE

9. This is a civil action for patent infringement and declaratory judgment arising under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

10. On information and belief, this Court has personal jurisdiction over Hetero USA and Hetero Labs.

11. Hetero USA and Hetero Labs have admitted that this Court has jurisdiction over them in *Forest Laboratories, Inc. et al. v. Torrent Pharmaceuticals Ltd. et al.*, C.A. No. 12-305 (D. Del.), D.I. 47, ¶ 42.

12. On information and belief, Hetero USA and Hetero Labs have availed themselves of this forum previously for the purpose of litigating a patent dispute. For example, Hetero USA and Hetero Labs have filed counterclaims for declaratory judgment.

13. On information and belief, Hetero USA is a Delaware corporation, is registered to do business in Delaware, and is the U.S. regulatory agent for Hetero Labs Limited Unit III.

14. On information and belief, Hetero Labs Limited Unit III is a division or part of Hetero Labs Ltd. Hetero Labs' website, located at http://www.heterodrugs.com/mfg-API-facilities.shtml, describes Unit III as an API manufacturing facility of Hetero Labs.

15. On information and belief, Hetero USA is in the business of marketing and selling generic prescription pharmaceutical drugs that it distributes in Delaware and throughout the United States. On information and belief, Hetero USA, either directly or through one or more of its subsidiaries, agents, and/or distributors, markets, sells, and/or distributes a substantial volume of its pharmaceutical products in Delaware. On information and belief, the acts of Hetero USA

complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of Hetero Labs. In letters dated March 29, 2013, April 1, 2013, and March 12, 2014 notifying AbbVie of the submission to the FDA of Hetero's ANDA No. 204587, Hetero USA described itself as "the U.S. Regulatory Agent for Hetero Labs Limited Unit III."

16. On information and belief, this court has personal jurisdiction over Hetero USA by virtue of, *inter alia*: (1) its incorporation in the State of Delaware; (2) its registration to do business in Delaware, including its appointment of a registered agent in Delaware for the receipt of service of process; (3) its course of conduct that is designed to cause the performance of tortious acts that will result in foreseeable harm in Delaware; (4) its purposeful availment of this forum previously for the purpose of litigating a patent dispute; and (5) its admission that it is subject to the Court's jurisdiction.

17. On information and belief, Hetero Labs formulates, develops, markets, and sells active pharmaceutical ingredients ("API"), solid oral dosage forms, pharmaceutical formulations, and/or pharmaceutical products containing such API or pharmaceutical formulations (collectively "Hetero's products"). Hetero Labs, through its U.S. regulatory agent, Hetero USA, routinely files ANDAs seeking FDA approval to market its products in the United States.

18. On information and belief, Hetero Labs, directly or through Hetero USA and/or through one or more of its wholly owned subsidiaries, affiliates, agents, distributors, or parent corporation is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in Delaware and throughout the United States. On information and belief, Hetero Labs, either directly or through Hetero USA and/or through one or more of its subsidiaries, agents, and/or distributors, formulates, manufactures,

markets, sells, and/or distributes a substantial volume of its pharmaceutical products in Delaware.

19. Hetero USA's acts and continuous and systematic contacts with the State of Delaware, as an agent of Hetero Labs, are also attributable to Hetero Labs for jurisdictional purposes.

20. On information and belief, Hetero USA and Hetero Labs operate as an integrated business ultimately controlled by Hetero Labs.

21. On information and belief, this judicial district is a likely destination of products that will be manufactured and sold as a result of FDA approval of Hetero's ANDA No. 204587, which is the subject of this lawsuit.

22. On information and belief, this Court has personal jurisdiction over Hetero Labs by virtue of, *inter alia*: (1) its presence in Delaware, including through Hetero USA; (2) its course of conduct that is designed to cause the performance of tortious acts that will result in the foreseeable harm in Delaware; (3) its purposeful availment of this forum previously for the purpose of litigating a patent dispute; and (4) its admission that it is subject to the Court's jurisdiction.

23. Hetero USA and Hetero Labs hereinafter are referred to collectively as "Hetero."

24. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and § 1400(b).

BACKGROUND

25. AbbVie is the holder of approved New Drug Application ("NDA") No. 22-417 for ritonavir tablets, which AbbVie markets and sells under the trademark Norvir®. AbbVie manufactures and sells Norvir® 100 mg tablets in the United States under NDA No. 22-417.

26. Hetero filed with the FDA ANDA No. 204587 under 21 U.S.C. § 355(j)(2)(B), seeking FDA approval to market ritonavir tablets 100 mg ("Hetero Labs' generic ritonavir tablets"), which are generic copies of AbbVie's Norvir® tablets.

27. Upon information and belief, ANDA No. 204587 seeks FDA approval of a pharmaceutical composition comprising ritonavir in a 100 mg dosage strength.

28. Upon information and belief, ANDA No. 204587 seeks FDA approval to market generic ritonavir tablets in the United States.

29. On March 13, 2014, AbbVie received a letter on behalf of Hetero, dated March 12, 2014, purporting to be a "Notification Pursuant to Section 505(j)(2)(B) [21 USC § 355(b)(4)(B)]" for ANDA No. 204587 pursuant to section 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act and 21 C.F.R. § 314.95(e). Hetero's March 12, 2014 Notice Letter notified AbbVie that Hetero had amended ANDA No. 204587, seeking approval to market generic ritonavir tablets prior to the expiration of the '015 and '347 patents.

THE PATENTS-IN-SUIT

30. The '015 patent was duly and legally issued by the PTO on March 19, 2013. AbbVie is listed as the assignee on the face of the '015 patent. AbbVie is the owner by assignment of the '015 patent and has the right to sue for infringement thereof. AbbVie lists the '015 patent in the Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") for NDA No. 22-417. A true and correct copy of the '015 patent is attached as Exhibit A. The '015 patent expires on February 25, 2025, inclusive of pediatric exclusivity.

31. The '347 patent was duly and legally issued by the United States Patent and Trademark Office ("PTO") on June 25, 2013. AbbVie Deutschland GmbH & Co. KG is the owner by assignment of the '347 patent and has the right to sue for infringement thereof. AbbVie lists the '347 patent in the Orange Book for NDA No. 22-417. A true and correct copy of the

'347 patent is attached as Exhibit B. The '347 patent expires on March 17, 2027, inclusive of pediatric exclusivity.

FIRST COUNT FOR PATENT INFRINGEMENT
UNITED STATES PATENT NO. 8,470,347 B2

32. Paragraphs 1–31 are incorporated herein by reference.

33. On information and belief, Hetero USA, on behalf of Hetero Labs, filed ANDA No. 204587 in order to obtain approval to market generic ritonavir tablets in the United States before the expiration of the '347 patent. On information and belief, ANDA No. 204587 identifies Hetero Labs as the manufacturer of the generic ritonavir tablets. On information and belief, Hetero filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '347 patent are purportedly invalid and/or not infringed.

34. On information and belief, Hetero USA and Hetero Labs acted in concert to seek FDA regulatory approval for generic ritonavir tablets manufactured by Hetero Labs. On information and belief, Hetero Labs actively and knowingly aided and abetted Hetero USA in the filing of ANDA No. 204587.

35. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 204587 seeking approval for the commercial marketing of Hetero Labs' generic ritonavir tablets before the expiration date of the '347 patent constitutes infringement of one or more claims of the '347 patent, either literally or under the doctrine of equivalents.

36. Hetero Labs' inducement of Hetero USA to file ANDA No. 204587 constitutes infringement under § 271(b).

37. On information and belief, under § 271(b), Hetero Labs has knowingly and actively induced and specifically intended the acts of Hetero USA that will constitute direct infringement upon approval of ANDA No. 204587.

38. On information and belief, under § 271(b), Hetero USA has knowingly and actively induced and specifically intended the acts of Hetero Labs that will constitute direct infringement upon approval of ANDA No. 204587.

39. Upon FDA approval of ANDA No. 204587, Hetero USA and Hetero Labs will each infringe one or more claims of the ’347 patent, either literally or under the doctrine of equivalents, under § 271(a) by making, using, offering to sell, selling, and/or importing generic ritonavir tablets, and by actively inducing infringement by others under § 271(b), unless this Court orders that the effective date of any FDA approval of ANDA No. 204587 shall be no earlier than the expiration date of the ’347 patent and any additional periods of exclusivity.

40. On information and belief, Hetero USA and Hetero Labs are aware and/or have knowledge that healthcare professionals and/or patients will use their generic ritonavir tablets according to the instructions in the proposed package insert in a way that directly infringes the ’347 patent.

41. The offering to sell, sale, making, and/or importation of generic ritonavir tablets would actively induce infringement of at least one of the claims of the ’347 patent, either literally or under the doctrine of equivalents. Hetero has knowledge and is aware of AbbVie’s ’347 patent, as evidenced by Hetero’s March 12, 2014 Notice Letter.

42. AbbVie will be irreparably harmed if Hetero is not enjoined from infringing or actively inducing infringement of at least one claim of the ’347 patent. Pursuant to 35 U.S.C.

§ 283, AbbVie is entitled to a permanent injunction against further infringement. AbbVie does not have an adequate remedy at law.

SECOND COUNT FOR PATENT INFRINGEMENT
UNITED STATES PATENT NO. 8,399,015 B2

43. Paragraphs 1–42 are incorporated herein by reference.

44. On information and belief, Hetero USA, on behalf of Hetero Labs, filed ANDA No. 204587 in order to obtain approval to market generic ritonavir tablets in the United States before the expiration of the '015 patent. On information and belief, ANDA No. 204587 identifies Hetero Labs as the manufacturer of the generic ritonavir tablets. On information and belief, Hetero filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '015 patent are purportedly invalid and/or not infringed.

45. On information and belief, Hetero USA and Hetero Labs acted in concert to seek FDA regulatory approval for generic ritonavir tablets manufactured by Hetero Labs. On information and belief, Hetero Labs actively and knowingly aided and abetted Hetero USA in the filing of ANDA No. 204587.

46. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 204587 seeking approval for the commercial marketing of Hetero Labs' generic ritonavir tablets before the expiration date of the '015 patent constitutes infringement of one or more claims of the '015 patent, either literally or under the doctrine of equivalents.

47. Hetero Labs' inducement of Hetero USA to file ANDA No. 204587 constitutes infringement under § 271(b).

48. On information and belief, under § 271(b), Hetero Labs has knowingly and actively induced and specifically intended the acts of Hetero USA that will constitute direct infringement upon approval of ANDA No. 204587.

49. On information and belief, under § 271(b), Hetero USA has knowingly and actively induced and specifically intended the acts of Hetero Labs that will constitute direct infringement upon approval of ANDA No. 204587.

50. Upon FDA approval of ANDA No. 204587, Hetero USA and Hetero Labs will each infringe one or more claims of the ’015 patent, either literally or under the doctrine of equivalents, under § 271(a) by making, using, offering to sell, selling, and/or importing generic ritonavir tablets, and by actively inducing infringement by others under § 271(b), unless this Court orders that the effective date of any FDA approval of ANDA No. 204587 shall be no earlier than the expiration date of the ’015 patent and any additional periods of exclusivity.

51. On information and belief, Hetero USA and Hetero Labs are aware and/or have knowledge that healthcare professionals and/or patients will use their generic ritonavir tablets according to the instructions in the proposed package insert in a way that directly infringes the ’015 patent.

52. The offering to sell, sale, and/or importation of generic ritonavir tablets would actively induce infringement of at least one of the claims of the ’015 patent, either literally or under the doctrine of equivalents. Hetero has knowledge and is aware of AbbVie’s ’015 patent, as evidenced by Hetero’s March 12, 2014 Notice Letter.

53. AbbVie will be irreparably harmed if Hetero is not enjoined from infringing and actively inducing infringement of at least one claim of the ’015 patent. Pursuant to 35 U.S.C.

§ 283, AbbVie is entitled to a permanent injunction against further infringement. AbbVie does not have an adequate remedy at law.

THIRD COUNT FOR DECLARATORY JUDGMENT AS TO THE '347 PATENT

54. Paragraphs 1–53 are incorporated herein by reference.

55. Upon further information and belief, Hetero intends to commence sales of such ritonavir tablets immediately upon receiving approval from the FDA.

56. On information and belief, Hetero has knowledge of the '347 patent and will knowingly induce infringement of the '347 patent, if the FDA approves ANDA No. 204587 before the expiration of the '347 patent. On information and belief, if the FDA approves ANDA No. 204587, Hetero Labs will import into the United States generic ritonavir tablets, despite an objectively high likelihood that Hetero Labs' importation into the United States, and Hetero USA's marketing, offering for sale, and sale, of Hetero Labs' generic ritonavir tablets in the United States will constitute infringement of a valid patent. On information and belief, this risk is either known or should be known to Hetero USA.

57. On information and belief, Hetero Labs' generic ritonavir tablets, if approved by the FDA, will be imported by Hetero into the United States, and marketed, offered for sale, and sold in the United States by Hetero USA, which will constitute direct infringement of 35 U.S.C. § 271(a) of the '347 patent by Hetero Labs. On information and belief, that importation, marketing, offering for sale, and sale will occur with Hetero USA's specific intent and encouragement, and will be conduct that Hetero USA knows or should know will occur. On information and belief, Hetero USA will actively induce, encourage, aid, and abet that conduct, with knowledge and specific intent that the conduct will be in contravention of the AbbVie's rights under the '347 patent.

58. If the FDA approves ANDA No. 204587, the import into the United States of generic ritonavir tablets by Hetero Labs for Hetero USA to market, offer for sale, and sale in the United States before the expiration of the ’347 patent will actively induce infringement by others under 35 U.S.C. § 271(b) by Hetero USA of one or more claims of the ’347 patent, either literally or under the doctrine of equivalents, , under 35 U.S.C. § 271(b).

59. Hetero’s threatened actions in actively aiding, abetting, encouraging, and inducing sales of such ritonavir tablets would infringe one or more claims of the ’347 patent.

60. A case or controversy exists between AbbVie and Hetero regarding the infringement and validity of the ’347 patent.

61. Under the totality of the circumstances, there is a substantial controversy between AbbVie and Hetero having sufficient immediacy and reality to establish declaratory judgment jurisdiction relating to Hetero’s threatened infringement of the ’347 patent.

62. AbbVie will be substantially and irreparably damaged and harmed by the infringing activities described above unless those activities are precluded by this Court. AbbVie does not have an adequate remedy at law.

FOURTH COUNT FOR DECLARATORY JUDGMENT AS TO THE ’015 PATENT

63. Paragraphs 1–62 are incorporated herein by reference.

64. Upon further information and belief, Hetero intends to commence sales of such ritonavir tablets immediately upon receiving approval from the FDA.

65. On information and belief, Hetero has knowledge of the ’015 patent and will knowingly induce infringement of the ’015 patent, if the FDA approves ANDA No. 204587 before the expiration of the ’015 patent. On information and belief, if the FDA approves ANDA No. 204587, Hetero Labs will import into the United States generic ritonavir tablets, despite an objectively high likelihood that Hetero Labs’ importation into the United States, and Hetero

USA's marketing, offering for sale, and sale, of Hetero Labs' generic ritonavir tablets in the United States will constitute infringement of a valid patent. On information and belief, this risk is either known or should be known to Hetero USA.

66. On information and belief, Hetero Labs' generic ritonavir tablets, if approved by the FDA, will be imported by Hetero into the United States, and marketed, offered for sale, and sold in the United States by Hetero USA, which will constitute direct infringement of 35 U.S.C. § 271(a) of the '015 patent by Hetero Labs. On information and belief, that importation, marketing, offering for sale, and sale will occur with Hetero USA's specific intent and encouragement, and will be conduct that Hetero USA knows or should know will occur. On information and belief, Hetero USA will actively induce, encourage, aid, and abet that conduct, with knowledge and specific intent that the conduct will be in contravention of the AbbVie's rights under the '015 patent.

67. If the FDA approves ANDA No. 204587, the import into the United States of generic ritonavir tablets by Hetero Labs for Hetero USA to market, offer for sale, and sale in the United States before the expiration of the '015 patent will actively induce infringement by others under 35 U.S.C. § 271(b) by Hetero USA of one or more claims of the '015 patent, either literally or under the doctrine of equivalents.

68. Hetero's threatened actions in actively aiding, abetting, encouraging, and inducing sales of such ritonavir tablets would infringe one or more claims of the '015 patent.

69. A case or controversy exists between AbbVie and Hetero regarding the infringement and validity of the '015 patent.

70. Under the totality of the circumstances, there is a substantial controversy between AbbVie and Hetero having sufficient immediacy and reality to establish declaratory judgment jurisdiction relating to Hetero's threatened infringement of the '015 patent.

71. AbbVie will be substantially and irreparably damaged and harmed by the infringing activities described above unless those activities are precluded by this Court. AbbVie does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, AbbVie respectfully requests that this Court enter judgment in its favor as follows:

(1) declaring that, under 35 U.S.C. § 271(e)(2)(A), Hetero USA's submission to the FDA of ANDA No. 204587 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Hetero Labs' generic ritonavir tablets before the expiration of the '347 patent was an act of infringement of the '347 patent;

(2) declaring that Hetero Labs' commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of generic ritonavir tablets would constitute infringement of the '347 patent;

(3) declaring that, under 35 U.S.C. § 271(e)(2)(A), Hetero Labs' active and knowing aiding and abetting of the submission to the FDA of ANDA No. 204587 to obtain approval for the sale and import of the generic ritonavir tablets by Hetero Labs for Hetero USA to market, offer for sale, and sell in the United States before the expiration of the '347 patent were acts of infringement of one or more claims of the '347 patent;

(4) declaring that Hetero would infringe one or more claims of the '347 patent under one or more of 35 U.S.C. §§ 271(a)–(b) by its manufacture, use, offering to sell, and sale

in, and importation into the United States of Hetero Labs' generic ritonavir tablets prior to expiration of the '347 patent and any additional dates of exclusivity therefor;

(5) ordering that the effective date of any FDA approval of Hetero Labs' generic ritonavir tablets shall be no earlier than the expiration date of the '347 patent and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

(6) enjoining Hetero Labs and all persons acting in concert with Hetero Labs, from commercially manufacturing, using, offering for sale, or selling Hetero Labs' generic ritonavir tablets within the United States or importing into the United States Hetero Labs' generic ritonavir tablets, until the expiration of the '347 patent, and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(B);

(7) enjoining Hetero USA and all persons acting in concert with Hetero USA, from commercially manufacturing, using, offering for sale, or selling or importing into the United States Hetero Labs' generic ritonavir tablets, until the expiration of the '347 patent, and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(B);

(8) enjoining Hetero and all persons acting in concert with Hetero, from seeking, obtaining, or maintaining approval of ANDA No. 204587 until the expiration of the '347 patent, and any additional periods of exclusivity;

(9) declaring the '347 patent valid and enforceable;

(10) declaring that, under 35 U.S.C. § 271(e)(2)(A), Hetero USA's submission to the FDA of ANDA No. 204587 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Hetero Labs' generic ritonavir tablets before the expiration of the '015 patent was an act of infringement of the '015 patent;

(11) declaring that Hetero Labs' commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of generic ritonavir tablets would constitute infringement of the '015 patent;

(12) declaring that, under 35 U.S.C. § 271(e)(2)(A), Hetero Labs' active and knowing aiding and abetting of the submission to the FDA of ANDA No. 204587 to obtain approval for the sale and import of the generic ritonavir tablets by Hetero Labs for Hetero USA to market, offer for sale, and sell in the United States before the expiration of the '015 patent were acts of infringement of one or more claims of the '015 patent;

(13) declaring that Hetero would infringe one or more claims of the '015 patent under one or more of 35 U.S.C. §§ 271(a)–(b) by its manufacture, use, offering to sell, and sale in, and importation into the United States of Hetero Labs' generic ritonavir tablets prior to expiration of the '015 patent and any additional dates of exclusivity therefor;

(14) ordering that the effective date of any FDA approval of Hetero Labs' generic ritonavir tablets shall be no earlier than the expiration date of the '015 patent and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

(15) enjoining Hetero Labs and all persons acting in concert with Hetero Labs, from commercially manufacturing, using, offering for sale, or selling Hetero Labs' generic ritonavir tablets within the United States or importing into the United States Hetero Labs' generic ritonavir tablets, until the expiration of the '015 patent, and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(B);

(16) enjoining Hetero USA and all persons acting in concert with Hetero USA, from commercially manufacturing, using, offering for sale, or selling or importing into the United

States Hetero Labs' generic ritonavir tablets, until the expiration of the '015 patent, and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(B);

(17) enjoining Hetero and all persons acting in concert with Hetero, from seeking, obtaining, or maintaining approval of ANDA No. 204587 until the expiration of the '015 patent, and any additional periods of exclusivity;

(18) declaring the '015 patent valid and enforceable;

(19) declaring this to be an exceptional case and awarding AbbVie its attorney fees under 35 U.S.C. § 285;

(20) awarding AbbVie its costs and expenses in this action; and

(21) awarding AbbVie any further and additional relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Mary B. Graham

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